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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/229,173	01/13/1999	DEB K. CHATTERJEE	0942.2800008	7438

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/229,173

Applicant(s)

CHATTERJEE, DEB K.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-10,13,16,17,19,26,28,29,34-38 and 40-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 and 40-44 is/are allowed.
- 6) ☒ Claim(s) 1,3,5-10,13,16,17,19,26,28,29 and 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/7/2004 has been entered.

Applicants amendment of claims 1, 10, 37 and 40, in the paper of 4/7/2004, is acknowledged. Claims 1, 3, 5-10, 13, 16, 17, 19, 26, 28, 29, 34-38, and 40-44 are still at issue and are present for examination.

Applicants' arguments filed on 4/7/2004, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5-10, 13, 16, 17, 19, 26, 28, 29 and 34-37 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 (claims 3, 5-10, 13, 16, 17, 19, 26, 28, 29 and 34-36 dependent on) and 37 are indefinite in the recitation "wherein said Thermotoga maritime (Tma) DNA polymerase has a molecular weight of about 100 kilodaltons" in that it is unclear if applicants are referring to the Thermotoga maritime (Tma) DNA polymerase prior to its modification or after its modification. An amendment such as "wherein said modified Thermotoga maritime (Tma) DNA polymerase has a molecular weight of about 100 kilodaltons" would help applicants overcome this rejection.

The previous rejection of claims 1, 3, 5-10, 13, 16, 17, 19, 26, 28, 29 and 34-37 under 35 U.S.C. 112, second paragraph, as being indefinite in that the recitation "...wherein said mutation is selected from the group consisting of: a deletion, a single or double substitution, a point mutation, a frame shift mutation and an insertion" is withdrawn based on applicants amendment of the claims.

It is further acknowledged and noted that in claim 1, "a mutation" may encompass "a deletion, a single or double substitution and an insertion". This is addressed specifically with respect to applicants claim that a mutation may encompass a double substitution, which might be interpreted by some in the art as two mutations. Additionally it is noted that "a mutation" is interpreted as referring to a single mutation selected from the group consisting of "a deletion, a single or double substitution and an insertion".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5-8, 10, 13, 16, 17, 19, 26, 28, 29 and 34-37 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is stated in the previous office actions, Paper No. 12, 11/21/2000, Paper No. 15, 7/30/2001, Paper No. 26, 5/1/2002 and the paper of 4/9/2003 and applicants traversals are found in Paper No. 14, 5/21/2001, Paper No. 20, 12/18/2001, Paper No. 26, 5/1/2002, Paper No. 31, 1/8/2003 and the papers of 10/9/2003 and 4/7/2004.

In response to the this rejection, applicants have amended claims 1, 10 and 37. Claims 1 and 37 have been amended to recite that "said mutation is selected from the group consisting of: a deletion, a single or double substitution and an insertion" and applicants traverse the rejection as it applies to the amended claims. While applicants have narrowed the scope of the claimed Tma DNA polymerase mutants, the amended claims remain rejected.

The rejected claims are now directed to all possible *Thermotoga maritima* (Tma) DNA polymerase mutants which are modified at least two ways selected from the group consisting of (a) a mutation in the 3'-5' exonuclease domain of said polymerase to reduce or eliminate the 3' 5' exonuclease activity of the polymerase; (b) a mutation in the 5'-3' exonuclease domain of said polymerase to reduce or eliminate the 5'-3' exonuclease activity of the polymerase; and (c) a mutation in the O-helix of said polymerase to reduce or eliminate discriminatory behavior against a dideoxynucleotide wherein said mutation is selected from the group consisting of: a deletion, a single or double substitution and an insertion, wherein said *Thermotoga maritima* (Tma) DNA polymerase has a molecular weight of about 100 kilodaltons and methods of using and kits comprising said DNA polymerase mutants and genes encoding said DNA polymerase mutants.

Applicants continue to traverse this rejection on the basis that the test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor has possession of the claimed invention in the specification as filed and applicants submit that the specification of the captioned application provides sufficient description of Tma DNA polymerase mutants, strong evidence of a function/structure relationship and adequate description of representative species. Rather than reiterate applicants previous arguments along these lines, applicants refer the examiner to the responses filed on, *inter alia*, May 21, 2001, December 18, 2001, January 8, 2009 and October 9, 2003.

Applicants note that during the previous examiner interview, applicants' representative reminded the examiner that an applicant is not required to disclose or provide a working example of every species of a given genus in order to meet the written description requirement of 35 U.S.C. 112. Rather applicants submit that a description of a genus may be achieved by a recitation of a representative number of embodiments falling within the scope of the genus. Applicants representative argued that the present specification describes a sufficient number of representative examples of the claimed genus. For example applicants submit that applicants' disclosure of a variety of mutations at any one of six conserved amino acids that are associated, including Asp⁸, Glu¹¹², Asp¹¹⁴, Asp¹¹⁵, Asp¹³⁷ and Asp¹³⁹ among others. Applicants further submit that applicants specification provides a number of experimental methods to construct, identify and assay mutant polymerase within the scope of the claims as well as the each of the 3'-5' and 5'-3' domains are well characterized in the art. Finally applicants submit that in spite of the claims recitation of an insertion and deletion mutations, the resultant polypeptide must still have a molecular weight of about 100 kilodaltons.

Applicants traversal and previous arguments as well as applicants amendment of the claims has been considered in full but continues to be found nonpersuasive, on the basis that while applicants have described a number of specific amino acid residues which upon mutation result in the described altered function, these specific mutations are not representative of the claimed genus of DNA polymerases that includes all possible *Thermotoga maritima* (*Tma*) DNA polymerase mutants which are modified at

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least two ways selected from the group consisting of (a) a mutation in the 3'-5' exonuclease domain of said polymerase to reduce or eliminate the 3' 5' exonuclease activity of the polymerase; (b) a mutation in the 5'-3' exonuclease domain of said polymerase to reduce or eliminate the 5'-3' exonuclease activity of the polymerase; and (c) a mutation in the O-helix of said polymerase to reduce or eliminate discriminatory behavior against a dideoxynucleotide wherein said mutation is selected from the group consisting of: a deletion, a single or double substitution and an insertion, wherein said *Thermotoga maritime* (Tma) DNA polymerase has a molecular weight of about 100 kilodaltons. Applicants attention is specifically directed to those mutations encompassed in parts a and b of claim 1 which include any of the specified mutations (i.e. deletions, single and double substitutions or insertions...) of either the 3'-5' or 5'-3' domain. Applicants submission that the claimed genus would not include an "infinite number of amino acid variants" is acknowledged and appreciated, however, the claimed genus does encompass a significantly large enough genus that applicants disclosure does not adequately describe the claimed genus.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1, 3, 5-8, 10, 13, 16, 17, 19, 26, 28, 29 and 34-37 are additionally rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

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the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention because applicants recitation and claim to the genus of modified Tma DNA polymerases having a "double substitution" is not supported by the original specification at the time of filing and is thus considered new matter. Specifically it is the recitation of a double substitution and the genus that would be limited to such that is considered new matter. While it is appreciated that applicants specification teaches and supports one, two and three modifications of a Tma DNA polymerase, and applicants have an example of a specific "double substitution" (i.e. see example 11), applicants do not have support to claim the genus represented or described by a "double substitution".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a long horizontal line extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
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rg
6/17/2004